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TOWNSEND and TOWNSEND and CREW LLP

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PATENT

Docket No.: 018158-018610US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Lawrence W. Stark et al.

Application No.: 10/006,992

Filed: December 6, 2001

For: DIRECT WAVEFRONT-BASED CORNEAL ABLATION TREATMENT PROGRAM

Technology Center: 3700

Confirmation No.: 1090

Examiner: David M. Shay

Art Unit: 3735

REPLY BRIEF

UNDER 37 CFR §41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is Appellants' Reply Brief in response to the Examiner's Answer mailed on February 9, 2007.

STATUS OF CLAIMS

Claims 1-17 and 21-35 are canceled. Claims 18-20 and 36-42 are pending, and stand rejected. Claims 43 and 44 are withdrawn. Claims 18-20 and 36-42 are appealed. All pending claims are presented in **Appendix A**.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 18-20 and 36-42 are directed to non-statutory subject matter under 35 U.S.C. §101.

B. Whether claims 18-20 and 36-42 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 6,563,105 to Seibel et al. ["Seibel"] in combination with U.S. Patent No. 6,280,435 to Odrich et al. ["Odrich"] and U.S. Patent No. 6,486,943 to Burns et al. ["Burns"].

ARGUMENT

A. Rejection under 35 U.S.C. §101

The only grounds of rejection apply to a group of claims (18-20 and 36-42). However in an Advisory Action mailed October 25, 2006, the Examiner states that the §101 rejection is not applicable to at least claim 39. Thus, claim 39 is argued separately.

Claims 18-20, 36-38, and 40-42

1. The Examiner's rationale

The Examiner's Answer (page 4) says that the §101 rejection is not based on the "mental steps" test for non-statutory subject matter, and clarifies that instead the rejection is based on an alleged lack of physical transformation, and a lack of a useful, concrete, and tangible result. Appellants submit that the Examiner's conclusion is incorrect.

2. Analysis

At a minimum, the step of "transmitting an image through the optical tissue" as recited in claim 18 provides a transformation of an article or physical object to a different state or thing, because the claimed "transmitted image" has been transformed to a different state. The transformative effect of an optical system, for example optical tissue, is described in U.S. Patent No. 6,486,943 to Burns et al. (which is part of the instant §103 rejection, and not new evidence):

> "A typical optical system operates on an incident optical wavefront to ***transform*** it to a ***different*** optical wavefront. Generally, different points on the wavefront experience different ***transformations*** depending on what portions of the optical system they encounter. [...] The wavefront encountering the lens results in a ***transmitted wavefront*** having a ***different*** shape." (See col. 1, lines 19-30; emphasis added).

Based on this transformative effect, Appellants submit that the claimed step of transmitting an image through the optical tissue provides a transformation of an article or physical object to a different state or thing (e.g. the claimed transmitted image), and thus is not a mere calculation.

Moreover, the claimed "accuracy of the gradient array" is more than a calculation, because it is a useful, concrete, and tangible result. It is possible to use the accuracy to

determine, for instance, whether to formulate a vision treatment based on the gradient array, as indicated in the instant specification at, for example, page 18, lines 14-15.

3. Conclusion

It has not been shown that the presently pending claims present non-statutory subject matter. Thus, the Examiner has not met the burden of establishing a *prima facie* case of unpatentability.

Claim 39

As noted above, in an Advisory Action mailed October 25, 2006, the Examiner states that the §101 rejection is not applicable to at least claim 39. Appellants affirm this conclusion, at minimum because the claimed step of "modifying the optical tissue surface according to the proposed change by laser ablation" goes beyond a mere calculation. The claimed step provides a transformation of an article or physical object to a different state or thing, and provides a useful, concrete, and tangible result. Thus, a *prima facie* case of unpatentability has not been made. Reversal of this outstanding rejection is respectfully requested.

B. Rejection under 35 U.S.C. §103 over Seibel in combination with Odrich and Burns

Claims 18-20 and 36-42

The only grounds of rejection apply to a group of claims (18-20 and 36-42), and the claims are argued as a group.

1. Analysis

The Seibel and Odrich references cannot properly be cited in a §103 rejection.

a. Applicable Law

According to MPEP 2141.01(I), "[b]efore answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. §102."

According to MPEP 706.02(I)(1)(I), a reference cited under former 35 U.S.C. §103 via 35 U.S.C. §102(e) cannot be used as prior art against a claimed invention if that cited subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. The reference

must be disqualified under the commonly assigned/owned prior art provisions of 35 U.S.C. 103(c).

b. The Instant Application

The instant application was filed 12/6/01, and claims priority to provisional application no. 60/254,313 filed 12/8/00. At the time the presently claimed invention was made, it was owned or subject to an obligation of assignment to VISX Incorporated.

c. USPN 6,563,105 to Seibel et al.

The Seibel application was filed 8/23/01, and published on 10/3/02. The patent issued 5/13/03. Seibel was not published before the instant application was filed, and thus *cannot qualify as a §102(a) reference*. Seibel was not published more than one year before the instant application was filed, and thus *cannot qualify as a §102(b) reference*. Seibel was filed before the instant application was filed but not before the instant priority provisional was filed. Support for the present pending claims can be found in the instant priority provisional application at, for example, page 11, line 11 to page 13, line 4, Figs. 5-6A, and the originally filed claims, including claims 1, 9, and 10. Thus, Seibel *cannot qualify as a §102(e) reference*. Because Seibel is not prior art under 35 U.S.C. §102, there is no need to proceed to Graham's content inquiry. In sum, according to MPEP 2141.01(I), Seibel cannot properly be included in the proposed §103(a) rejection.

d. USPN 6,280,435 to Odrich et al.

The Odrich application was filed 3/3/99, and issued 8/28/01. The Odrich application claims priority to provisional application no. 60/076,786 filed 3/4/98. Odrich was published before the instant application was filed, but not before the instant provisional application was filed, and thus *cannot qualify as a §102(a) reference*. Odrich was not published more than one year before the instant application was filed, and thus *cannot qualify as a §102(b) reference*. Odrich was filed before the instant application was filed and the Odrich provisional was filed before the instant provisional, and thus Odrich *can only qualify as a §102(e) reference*. Odrich was, at the time the presently claimed invention was made, owned by or subject to an obligation of assignment to VISX Incorporated. Thus, Odrich, which could only qualify under 102(e), shall not preclude patentability because of the *common ownership* provisions of 35 U.S.C.

§103(c). In sum, according to MPEP 706.02(I)(1)(I), Odrich cannot properly be included in the proposed §103(a) rejection.

e. Substantive Issues

Notwithstanding the above, Appellants submit that the Examiner's Answer has not shown that the artisan would be motivated to apply the image processing method of Seibel to the wavefront aberration data of Burns. The wavefront aberration data of Burns is generated by light *transmitted through* the cornea, lens, and fluids of the eye, as described at col. 8, line 43 to col. 11, line 49 and depicted at Fig. 4. In contrast, Seibel's method evaluates data based on light that is *reflected off the surface* of an object, as described at col. 15, lines 10-26 and depicted at Fig. 22. It has not been shown that the artisan would be motivated to apply Seibel's topographical surface imaging process to Burns' subsurface wavefront aberration data, with a reasonable expectation that the proposed combination would function properly as concluded in the Examiner's Answer. The Examiner's Answer also alleges that because the specification reports that "[a]n accuracy of at least one of the gradients of the gradient array may be determined by calculating a change in elevation along a closed integration path," it logically follows that the step of performing the integration ***is*** the determination of the accuracy of the array. As stated in the Appeal Brief, it is possible to perform an integration without determining accuracy, and thus the legal requirements for an inherency rejection have not been met.

2. Conclusion

It is improper to include Seibel and Odrich in the §103(a) rejection. It has not been shown that the cited references when combined teach all the claim elements, nor has any motivation to combine the references been established that is not based on hindsight. Thus, the Examiner has not met the burden of establishing a *prima facie* case of obviousness. Reversal of this outstanding rejection is respectfully requested.

CLAIMS APPENDIX

A copy of the claims involved in the appeal is attached as Appendix A.

Respectfully submitted,

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Attachments:

- **Appendix A: Claims**

Appendix A: Pending claims

1-17. (Canceled)

18. (Previously Presented) A method of determining an accuracy of a gradient array in an optical tissue measurement comprising:

transmitting an image through the optical tissue;

determining local gradients of the array across the optical tissue from the transmitted image;

integrating along a closed integration path across a portion of the array; and

determining the accuracy of the gradient array based on the integration.

19. (Original) The method of claim 18, further comprising:

calculating a change in elevation along the closed integration path across the portion of the array.

20. (Original) The method of claim 18 wherein, the closed integration path comprises:

a common starting point, a common ending point, a first integration path connecting the common starting point to the common ending point, and a second integration path connecting the common starting point to the common ending point, the first and second integration paths being different.

21-35. (Canceled)

36. (Previously Presented) The method of claim 18, further comprising transmitting a source image from a light source posteriorly through the optical tissues and onto the retina to define the image, wherein the image is transmitted posteriorly through a central region of the cornea, the central region having a size which is significantly less than a pupil size

of the eye, and wherein the image is transmitted from the retina anteriorly through the optical tissues.

37. (Previously Presented) The method of claim 36, wherein the image is transmitted by the optical tissues as a plurality of beamlets, wherein each gradient corresponds to an associated portion of an optical surface such that each beamlet is transmitted through the optical tissue according to the corresponding gradient.

38. (Previously Presented) The method of claim 18 wherein the integration is performed so as to map an error-correcting change in optical tissues.

39. (Previously Presented) The method of claim 38 wherein the mapping step comprises deriving a proposed change in the optical tissue surface elevations so as to effect a desired change in optical properties of the eye, and further comprising modifying the optical tissue surface according to the proposed change by laser ablation.

40. (Previously Presented) The method of claim 18, wherein the closed integration path extends from a first center of a first portion of the optical surface to a second center of a second portion of the optical surface, from the second center to a third center of a third portion of the optical surface, and from the third center back to the first center, the first, second and third portions of the optical surface corresponding to the first, second and third gradients of the gradient array, respectively.

41. (Previously Presented) The method of claim 18, wherein the closed integration path extends from an initial location corresponding to a position between a first gradient array element and a second gradient array element, the path crossing a first portion of the optical surface corresponding to the second gradient array element, a second portion of the optical surface corresponding to a third gradient array element, and a third portion of the optical surface corresponding to a fourth gradient array element before returning back to the initial location.

42. (Previously Presented) The method of claim 18, wherein an elevation map is generated directly in the mapping step without deriving coefficients of a series expansion mathematically approximating the optical surface.

43. (Withdrawn) A method of identifying an inaccuracy of a gradient array corresponding to an optical tissue, comprising:

inputting a gradient array corresponding to light transmitted through an optical tissue;

integrating along a first closed integration path on the gradient array to determine a first path integration, the first integration path comprising a common starting point and a common ending point;

integrating along a second closed integration path on the gradient array to determine a second path integration, the second path comprising the common starting point and the common ending point; and

identifying the inaccuracy of the gradient array by comparing the first path integration with the second path integration.

44. (Withdrawn) A method of identifying an inaccuracy of a gradient array corresponding to an optical tissue, comprising:

inputting a gradient array corresponding to light transmitted through the optical tissue;

integrating along a first closed integration path on the gradient array to determine a first path integration, the first integration path comprising a common starting point and a common ending point;

integrating along each of a set of additional closed integration paths on the gradient array to determine a corresponding set of additional path integrations, each of the additional closed integration paths comprising the common starting point and the common ending point; and

identifying the inaccuracy of the gradient array by comparing the first path integration with the set of additional path integrations.